K120460

5. 510(k) Summary

OCT 1 2012

See 510(k) Summary, below.

Medmix Co., Ltd.

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1. Submission Correspondent: Peter Chung

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300 Atwood Street Pittsburgh, PA 15213 USA

Date: May 12th, 2012

2. Trade Name: . SMARTLUX
Common Name : Visible and Infrared Light Source
Product Code: GEX
Regulation: 878.4810
Class of device : ClassII.

3. Description of device:

SMARTLUX is light therapy system using two kinds of wave length light and infrared ray.
It has four type of head which is including red, blue and IR respectively.
Heads are changeable by user and assembled head is identified automatically
after changing head and user interface is also changed according to each head.
For the safety of device operation, there are emergency switch and key switch so operator can control by touch screen based on MEDMIX's software.

▪ Head type

SMARTLUX has ten type of heads for patient treatment. Below table shows the wave length of the light for each head.

Head Name	RED 633nm	BLUE 415nm	IR 830nm
SMARTLUX – RED	o		
SMARTLUX – BLUE		o	
SMARTLUX – IR			o
SMARTLUX – FX	o		o

4. Predicate Devices

- Wave length of red head in SmartLux are 633nm and pulse type is continuous which are equal with Omnilux Revive(K030426)

5. 510(k) Summary

- Wave length of blue head in SmartLux are 415nm and pulse type is continuous which are equal with Omnilux Blue (K030883)
- Wave length of IR, FX head in SmartLux are 830 nm and pulse type is continuous which are equal with Omnilux Plus (K043317)

5. Intended use

633nm wave length : Dermatology for treatment of superficial, benign vascular, and pigmented lesions

415nm wave length : Dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris

830nm wave length : the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

6. Performance test

- Performance test is performed as per EN 60601-2-22: Medical electrical equipment Part 2: Particular requirements for the safety of diagnostic and therapeutic laser Equipment
  - Performance Test Report for Temperature of therapeutic heat

The test data is attached

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 1 2012

Medmix Company, Limited
% Mr. Peter Chung
President
300 Atwood
Pittsburgh, Pennsylvania 15213

Re: K120460
Trade/Device Name: SMARTLUX
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 18, 2012
Received: September 26, 2012

Dear Mr. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

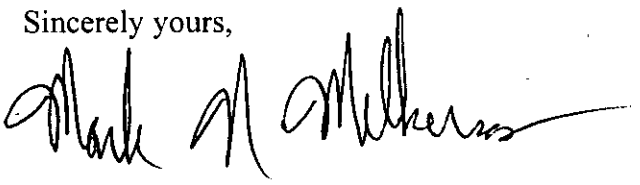
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K120460

Device Name: Visible and Infrared Light Source

Indications For Use:

633nm wave length : Dermatology for treatment of superficial, benign vascular, and pigmented lesions

415nm wave length : Dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris

830nm wave length : the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R.P. Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120460